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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,329	03/18/2005	Gabor Butora	21054P	6299
210	7590	09/19/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			NOLAN, JASON MICHAEL	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/528,329

Applicant(s)

BUTORA ET AL.

Examiner

Jason M. Nolan, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-27 are currently pending in the instant application and are subject to a lack of unity restriction requirement.

Response to Restriction

Applicants' election with traverse of **Group I, Claims 1-23** is acknowledged. Traversal is based on Applicants' opinion that all of the compounds recited in **Claims 1-23** share numerous common structural features and that a serious search burden does not exist for the Examiner. Examiner points out that there is a lack of unity since the technical feature is not a special technical feature because it fails to define a contribution over the prior art (see *v. Braun, J. Ber. (1909)*, 42, 2035-57). The Examiner also points out that an attempt to search even the elected group is a serious search burden such that a comprehensive search is not possible. Preliminary searching revealed over 19,000 compounds in less than 39% of the CAPLUS database. For these reasons, the previous Lack of Unity Restriction Requirement is withdrawn in lieu of this new grouping of distinct inventions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Claims 1-27 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

Art Unit: 1626

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,...."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to numerous and widely divergent variables in the substituents, for example: **W, X, and R¹⁻¹²**, and the numerous and widely divergent methods of use present, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I, Claims 1-23, drawn to products of the Formula I, wherein **W** = C, **n** = 0-1 (there are two **n**'s: so if **n** = 0, it is a 4-membered ring and if **n** = 1, it is a 6-membered ring), **X** and **R**^{1 & 5-12} are as defined, and **R**³ & **R**⁴ are joined together to form a ring.

Group II, Claims 1-23, drawn to products of the Formula I, wherein **W** = C, **n** = 0-1 (there are two **n**'s: so if **n** = 0, it is a 4-membered ring and if **n** = 1, it is a 6-membered ring), **X** and **R**^{1-4 & 9-12} are as defined, and either **R**⁵ & **R**⁸ or **R**⁶ & **R**⁷ are joined together to form a ring.

Group III, Claims 1-23, drawn to products of the Formula I, wherein **W** = C, **n** = 0-1 (there are two **n**'s: so if **n** = 0, it is a 4-membered ring and if **n** = 1, it is a 6-membered ring), **X** and **R**^{1-2 & 7-12} are as defined, and either **R**⁵ & **R**³ or **R**⁶ & **R**⁴ are joined together to form a ring.

Group IV, Claims 1-23, drawn to products of the Formula I, not defined in **Groups I-III** (i.e. **n** = 2 or 3).

Group V, Claims 1-23, drawn to products of the Formula I, wherein **W** = N, and **n** = 0-1.

Group VI, Claims 1-23, drawn to products of the Formula I, wherein **W** = N, and **n** = 2-3.

Group VII, Claims 1-23, drawn to products of the Formula I, wherein **W** = O, and **n** = 0-1.

Group VIII, Claims 1-23, drawn to products of the Formula I, wherein **W** = O, and **n** = 2-3.

Art Unit: 1626

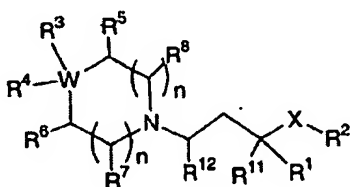
Group IX, Claims 24-27, drawn to methods of using the compounds according to Formula I.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this is not an exhaustive list, as it would be impossible to produce such a list under the time constraints due to the large volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product, a process of making the product and a method of use) by identifying another specific embodiment, i.e. a group containing the variables **W, X, and R⁶⁻¹²**, not listed in the exemplary groups of the invention and Examiner will endeavor to group the same. The applicant may also choose to elect a single disclosed species or a single method of use of a single species and the Examiner will endeavor to create a group comprising the elected species.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Group I - Group IX** lack unity of invention since, under 37 CFR 1.475:

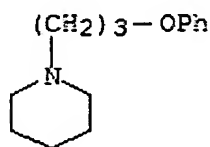
Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-IX** is the structural core shown below.



Art Unit: 1626

This technical feature is not a special technical feature, because it fails to define a contribution over the prior art shown below, (see v. Braun, J. *Ber.* (1909), 42, 2035-57).



Therefore, **Claims 1-27** are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Specifically, the products of Formula I introduce substituent **W**, wherein the structure may contain a nitrogen atom, a carbon atom, or an oxygen atom, resulting in patentably distinct structural cores. Furthermore, changes such as these affect the structural element shared by the products of Formula I, and represent a different class of chemical compounds in the pharmaceutical art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product and a method of use.

Art Unit: 1626

Furthermore, with respect to **Group I – Group IX**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than a product and a method of use, and according to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention.

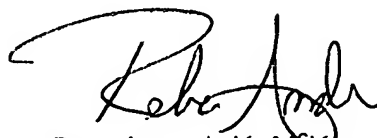
Art Unit: 1626

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^cKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.
Examiner
Art Unit 1626



& Joseph K. M^cKane
Supervisory Patent Examiner
Art Unit 1626
Date: September 6, 2006